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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOWERS, NATHAN ANDREW	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,212	WELTER ET AL.	
	Examiner	Art Unit	
	NATHAN A. BOWERS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *15-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. More specifically, the originally filed specification does not teach that two *identical* gas permeable membranes are provided. Applicant has not indicated where the specification teaches that both membranes are characterized by identical pore diameter, materials, size, etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-9, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Vetillard (WO 0206441) – see English language (US 20040132175) for a translation.

With respect to claim 1, Vetillard discloses a bioreactor comprising a housing (Figure 1:C2) defining a first chamber that contains a first liquid medium. The housing comprises an inlet port (Figure 1:EF2) and an outlet port (Figure 1:SF2) to accommodate a culture medium fluid flow through the first chamber. This is disclosed in paragraphs [0080] and [0096] of US 20040132175. Gas permeable membranes (Figure 1:M1 and Figure 1:M3) define a portion of the housing and allow gas to flow through the housing into the first chamber. Hydrostatic loading modules (Figure 1:C1 and Figure 1:C3) are provided for transmitting hydrostatic pressure through the membranes to the first liquid medium contained in the first chamber. Paragraphs [0109], [0134] and [0140]-[0146] indicate that a "downward phase" and an "ascending phase" are created by varying pressures within the hydrostatic loading modules.

With respect to claim 2, Vetillard discloses the apparatus in claim 1 wherein the hydrostatic loading module is capable of transmitting pressure by a static second liquid medium. Although Vetillard does not expressly indicate that fluid is retained at a static state within the loading modules before release through the outlet, the device of Vetillard is fully capable of being operated according to this intended use.

With respect to claims 3 and 9, Vetillard discloses the apparatus in claim 1 wherein the hydrostatic modules are attached to the housing and form second and third chambers with the housing. The second and third chambers are separated from the first chamber by gas permeable membranes. This is depicted in Figure 1.

With respect to claims 4 and 5, Vetillard discloses the apparatus in claim 3 wherein the hydrostatic loading modules include pumps (Figure 6:P1 and Figure 6:P3) for increasing and decreasing the pressure of each loading module.

With respect to claim 6, Vetillard discloses the apparatus in claim 4 wherein each loading module comprises an electronic pressure gauge for monitoring pressure in each chamber. This is described in paragraph [0144].

With respect to claims 7 and 8, Vetillard discloses the apparatus in claim 1 wherein the housing comprises a frame that includes a first surface spaced apart from a second surface. The walls of the housing depicted in Figure 1 are considered to represent first and second surfaces. The fluid inlet and fluid outlet are considered to be openings that extend through the frame.

With respect to claim 12, Vetillard discloses the apparatus in claim 1 wherein a pH sensor is provided. This is disclosed in paragraph [0106].

With respect to claim 14, Vetillard discloses the apparatus in claim 1 wherein control valves are provided for regulating fluid flow through inlets and outlets. This is described in paragraphs [0109], [0115] and [0117], and is shown in Figure 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 10, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vetillard (WO 0206441) as applied to claim 1, and further in view of Jensen (US 20040077075).

With respect to claim 10, Vetillard discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejections above, however does not expressly indicate that the membrane is optically transparent.

Jensen discloses a bioreactor comprising a plurality of chambers divided by a plurality of membranes (see Figure 2A). Jensen teaches that the gas permeable membranes are constructed from optically transparent materials. This is described throughout the reference and is presented in claim 19.

Vetillard and Jensen are analogous art because they are from the same field of endeavor regarding bioreactors comprising gas permeable membranes.

At the time of the invention, it would have been obvious to ensure that the membranes disclosed by Vetillard are constructed from optically transparent materials. Jensen teaches that this is beneficial because it allows one to better detect cell growth and metabolism using sensors that rely on bioluminescence. As evidenced by Jensen, biocompatible optically transparent membrane materials are readily available in the art.

With respect to claim 11, Vetillard and Jensen disclose the apparatus set forth in claim 10 as set forth in the 35 U.S.C. 103 rejection above. In addition, Jensen teaches in paragraph [0103] that the interior surfaces of the bioreactor are coated with a material resistant to cell attachment. Claims 28 and 29 further disclose the use of a substance that decreases adsorption of cells.

At the time of the invention, it would have been obvious to ensure that the gas permeable membrane disclosed by Vetillard was coated by a material resistant to cell attachment. One of ordinary skill in the art would have found it desirable to prevent attachment of cells to the Vetillard membrane in order to avoid clogging of the

membrane pores. As evidenced by Jensen, coatings that decrease adsorption of cells to a surface are known in the art.

With respect to claim 13, Vetillard discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. In addition, Jenson states in paragraphs [0161] and [0176] that magnetic stir bars are used to agitate the cell solution during fermentation.

At the time of the invention, it would have been obvious to use the magnetic impellers disclosed by Jensen in the first liquid medium chamber disclosed by Vetillard. Jensen teaches that magnetic stir bars are well known in the art, simple in operation, and effective in agitating and aerating a solution.

3) Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vetillard (WO 0206441) as applied to claim 1, and further in view of Puchinger (US 4225671).

Vetillard discloses the apparatus set forth in claim 1, however does not expressly state that the gas permeable membranes are identical.

Puchinger discloses a bioreactor comprising a housing defining a first chamber (Figure 1:104) with boundaries defined by gas permeable membranes (Figure 1:102 and Figure 1:103). Culture medium spaces (Figure 1:105 and Figure 1:106) are provided on opposite sides of each membrane. This is disclosed in column 3, line 61 to column 4, line 9.

Vetillard and Puchinger are analogous art because they are from the same field of endeavor regarding bioreactors comprising gas permeable membranes.

At the time of the invention, it would have been obvious to ensure that the Vetillard membranes were identical. Puchinger indicates in column 3, line 61 to column 4, line 9 that it is known in the art to provide membrane pairs that are either identical or different depending on the requirements of the particular cell culture system at hand. More specifically, Puchinger indicates that it is known to construct membranes that are specific to the type of culture medium space and/or gas space with which they interact. Accordingly, one of ordinary skill in the art would have recognized that it would have been beneficial to ensure that the Vetillard membranes were identical if both of the membranes interact with the same type of culture fluid or are intended to perform the same function.

Response to Arguments

Applicant's arguments filed 17 February 2009 with respect to the 35 U.S.C. 102 rejections involving Vetillard have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Vetillard does not disclose a hydrostatic loading module.

In response, please consider the following remarks.

Vetillard discloses a bioreactor that is structurally identical to the invention set forth in independent claim 1. As noted above, Vetillard discloses a housing comprising a first chamber defined by two gas permeable membranes. Fluidic modules are

provided on opposite sides of each gas permeable membrane. Even if, for the sake of argument, Vetillard does not disclose the use of hydrostatic pressure, the apparatus of Vetillard is fully capable of transmitting hydrostatic pressure through each membrane to the first chamber. In paragraphs [0060]-[0068], Applicant indicates that hydrostatic pressure is achieved by pressurizing the second chamber to promote gas exchange. Likewise, Vetillard teaches that fluids are introduced into a second chamber so as to pressurize the second chamber and subsequently promote gas exchange.

Accordingly, there is no reason to believe that the Vetillard system is incapable of being operated according to the hydrostatic pressure intended use set forth in claim 1. In response to applicant's argument that Vetillard does not disclose hydrostatic pressure, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797